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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,265	12/03/2001	Masatsugu Maeda	06501-096001 / C2-105DP1P	5055

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,265	MAEDA ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *9-19 and 28-31* is/are withdrawn from consideration.

5)☒ Claim(s) *1,3,20 and 21* is/are allowed.

6)☒ Claim(s) *2,4-8 and 22-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/06 has been entered. Applicant's amendment and response also received on 6/21/06 have been entered. Claims 1-31 are pending in the instant application. Claims 9-19 and 28-31 remain withdrawn from consideration as being drawn to an invention non-elected without traverse in the paper filed on 1/10/05. Claims 1-8, and 20-27 are currently under examination. An action on the merits follows. Please note that the examiner of record for this application has changed, see the last page of this office action.

Those sections of Title 35, US code, not included in this action can be found in previous office actions.

37 CFR 1.121

Applicant's claim amendment filed on 6/21/06 fails to comply with the requirements of 37 CFR 1.121. The claim amendment contains the wrong status identifiers for claims 28-31. The amendment lists claims 28-31 as "Previously presented". However, these claims were withdrawn from consideration by previous examiner as being drawn to an invention non-elected without

traverse, see the office action mailed on 12/21/05. These claims should have identified as "Withdrawn". As the errors in the claim amendment did not preclude examination, the amendment has been entered and considered by the examiner. However, future amendments to the claims must comply with 37 CFR 1.121(c). Otherwise, the applicant will receive a Notice of Non-Compliant Amendment under 37 CFR 1.121.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 5/9/06 and 6/21/06 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been being considered by the examiner.

Specification

The objection to the specification for containing an embedded hyperlink is withdrawn in view of applicant's amendment to the specification.

Claim Rejections - 35 USC § 112

The rejection of claims 1-8, and 20-27 under 35 U.S.C. 112, second paragraph, for indefiniteness is withdrawn in view of applicant's amendments to the claims.

Upon further consideration, the following new grounds of rejection under 35 U.S.C. 112, second paragraph, have been applied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7, 22-23, and 27 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-7, 22-23, and 27 are drawn to a "transformant". The term "transformant" is not specifically defined in the specification such that the metes and bounds of the claim can be determined. The specification primarily discloses transforming isolated cells, either prokaryotic or eukaryotic, with a vector *in vitro*. However, the specification also discloses the *in vivo* transformation of an animal. As such, it is unclear whether a "transformant" includes cell within an animal or the whole animal itself. If applicant intends "transformant" is include an animal then the applicant is advised that the claims would then read on a human being, which is not patentable subject matter. The examiner suggests amending the claims to recite " An isolated transformed cell.." in order to overcome the instant rejection.

Claims 5-7, 22-23, and 27 are further indefinite in their use of the term "harboring". Since it is unclear whether a transformant is a single cell or a whole organism or animal, it is unclear what is meant by "harboring" a nucleic acid or vector. If the transformant is a whole organism, it is unclear what locations are encompassed by "harboring", such as inside a cell, or in a stomach, or in the blood. As such the metes and bounds of the claim cannot be determined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-27 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 24 recites an isolated nucleic acid comprising a nucleotide sequence encoding a protein that comprises the amino acid sequence of SEQ ID NO: 2, 4, or 17, with a single amino acid replacement, deletion, insertion, or addition, wherein the protein binds to a hematopoietin factor. The claim broadly encompasses numerous different nucleic acid sequences as there are between as many as 663 amino acids in SEQ ID NO:17. However, the specification does not identify any specific amino acid in any of the claimed sequences that can be deleted or replaced, or identify positions in the proteins where an additional amino acid can be added or inserted such that binding to a hematopoietin factor is preserved.

The specification discloses the cloning of three related nucleic acid sequences, referred to as NR10.1, NR10.2, and NR10.3. The specification discloses that each nucleic acid comprises a coding region for a putative protein, and that the putative proteins share substantial homology. Specifically, the specification discloses that NR10.2 is a splice variant of NR10.1 and that NR10.3 is largely identical to NR10.1 except that the cytoplasmic domains differ as the result of a frameshift mutation in the nucleic acid sequence coding for the cytoplasmic domain. However, while the specification predicts from a comparison of the sequences of these putative proteins to

database sequences that the NR10 proteins are hematopoietin receptors, the specification provides no guidance as to the characteristics or identify of any ligand that binds to any one of these NR10 proteins. The specification is silent as to the physical, chemical, structural, and functional properties of a putative NR10 ligand. In the absence of any known ligand for NR10, or hematopoietin factor which binds to NR10, the skilled artisan would not be able to predict whether any single amino acid replacement, deletion, insertion, or addition to any portion of the NR10 proteins, or particularly the extracellular domain of these proteins would affect the binding of the putative receptor protein to a hematopoietin factor. As such , it would require undue experimentation for the skilled artisan to identify putative ligands for the three disclosed receptor proteins and then further test which of amino acids present in the receptor proteins can be replaced or deleted, or which amino acid can be inserted or added without affecting the ability of the receptor to bind to a ligand.

Claim Rejections - 35 USC § 101

The rejection of claims 1-8 and 20-27 under 35 U.S.C. 101, for lack of utility, is withdrawn in view of applicant's arguments. The specification asserts a utility for the claimed nucleic acids and transformants which is to make a polypeptide comprising SEQ ID NOS 2, 4, and 17 (also referred to as NR10.1, NR10.2, and NR10.3). The specification identifies specific utilities for the protein as its use in "the treatment of disease in which NR10 is implicated, such as leukemia", or in the treatment of inflammatory or allergic diseases. The office finds this specific utility to be substantial. Applicant's reference to example 3 of the Revised Interim

Utility Guidelines was deemed relevant to the instant claims in terms of determining whether the asserted utility was substantial. Further, the asserted utility meets the standard for a "credible" utility. As such, the rejection of the claims for a lack of utility is withdrawn.

The rejection of claims 1-8 and 20-27 under 35 U.S.C. 112, first paragraph, for lack of enablement based on the lack of an asserted specific, substantial, and credible utility is withdrawn in view of applicant's arguments, see the comments above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 4, 6, and 8 rejected under 35 U.S.C. 102(e) as being anticipated by U.S> Patent No. 6,642,360 (11/4/03), hereafter referred to as Filvaroff et al.. The applicant claims an isolated nucleic acid comprising a nucleotide sequence encoding a fragment of an amino acid sequence of SEQ ID NO:2, 4, or 17, a vector comprising the nucleic acid, and a transformant harboring the nucleic acid or vector comprising the nucleic acid.

Filvaroff et al. teaches an isolated nucleic acid, SEQ ID NO:90, which encodes a polypeptide, SEQ ID NO:91, which has 100% sequence identity to a fragment of SEQ ID NOS:

2, 4, and 17 (Filvaroff et al., Figures 33 and 34, and columns 14-15). Filvaroff et al. further teaches a vector comprising the nucleic acid, and a host cell transfected with the vector (Filvaroff et al., column 15). Thus, by teaching all the limitations of the instant invention as claimed, Filvaroff et al. anticipates claims 2, 4, 6, and 8.

Allowable Subject Matter

Claims 1, 3, 20, and 21 are considered free of the prior art and allowable at this time.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your

application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER